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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,717	05/02/2001	Soren Nielsen	NIELSEN=3B	3818
7590 02/01/2007 BROWDY AND NEIMARK, P.L.L.C. 624 Ninth Street, N.W. Washington, DC 20001			EXAMINER DEBERRY, REGINA M	
			ART UNIT	PAPER NUMBER
			1647	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/01/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/845,717	NIELSEN ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5,20,23,25-30,35,39-42 and 44-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,23,26-30,39-42,46,50 and 53 is/are rejected.
- 7) ☒ Claim(s) 20,25,35,44,45,47-49,51 and 52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Status of Application, Amendments and/or Claims***

Applicant's arguments (15 November 2006) have been entered in full. Claims 1, 2, 5, 20, 23, 25-30, 35, 39-42, 44-53 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claim Rejections - 35 USC § 103(a)**

Claims 1, 2, 5, 23, 39 and 53 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Akamatsu *et al.*, US Patent No. 4,745,099 in view of Anagnostou *et al.*, US Patent 5,922,674. The basis for this rejection is set forth at pages 3-5 of the previous Office Action (31 May 2006).

Applicant reiterates the Examiner's previous Office Action. Applicant states that they agree with the Examiner that Anagnostou *et al.* describe the use of EPO to treat endothelial injury. Applicant argues that in the reference, it is described that EPO effectively can prevent and/or repair endothelial damage caused by e.g. inflammation. Applicant asserts that lungs are lined with epithelial cells and not endothelial cells. Applicant contends that epithelial and endothelial cells are different cell types which possess different functions. Applicant submits definitions of endothelium and epithelium for the Wikipedia encyclopedia. Applicant states, "in general, endothelium cells in contrast to alveolar epithelium cells do not have marked transepithelial transport

capacities for solutes". Applicant maintains that the umbilical vein endothelium cells employed by Anagnostou et al. are not representative of lung epithelial cells.

Applicant's arguments have been fully considered but are not deemed persuasive. Applicant does not provide any evidence to support the assertion, "in general, endothelium cells in contrast to alveolar epithelium cells, do not have marked transepithelial transport capacities for solutes". Furthermore, the Examiner is unclear the point Applicant is trying to make with this statement. It is known to those skilled in the art that **lungs comprise both epithelial and endothelial cells**. Smith et al. (Chest, Vol 114/1, pages 337-340 July 1998) teach extensive involvement of lung microvascular endothelial cells by the cytomegalovirus (CMV) from an autopsy of an AIDS patient. In each of the histologic sections of the lung, numerous enlarged, CMV-infected endothelial cells were present within the alveolar septal capillaries (abstract, page 337, Pathologic Findings, 1st paragraph). Pettersson et al. (Infection and Immunity, Vol 73/11, pages 7736-7746 Nov. 2005) teach an animal model to study *Plasmodium falciparum malaria*. *Plasmodium falciparum* infected and non-infected human RBC were radiolabeled and injected into the tail vein of rats. The infected RBC accumulated in the lungs of the rats (page 7738). Pettersson et al. examined histological sections of rat lungs. Pettersson et al. teach infected RBC in the vicinity of the endothelium and some adhering to endothelial cell from the lung sample (page 7740, last paragraph-page 7741, 2nd paragraph; Figures 5 and 6B).

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

### **Claim Rejections - 35 USC § 103(a)**

Claims 26-30, 40-42, 46 and 50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Akamatsu *et al.*, US Patent No. 4,745,099 and Anagnostou *et al.*, US Patent 5,922,674 as applied to claims 1 and 39 above, and further in view of Delgado Hernandez *et al.*, Neuroimmunomodulation 6:187-192, 1999. The basis for this rejection is set forth at pages 5-8 of the previous Office Action (31 May 2006).

Applicant incorporates their response to the rejection under 35 USC 103(a) as being unpatentable over Akamatsu *et al.*, US Patent No. 4,745,099 in view of Anagnostou *et al.*, US Patent 5,922,674, in response to the instant rejection under 35 USC 103(a). Applicants arguments have been fully considered but are not found to be persuasive for the reasons discussed above in the maintained rejection in 35 USC 103(a) above and reasons of record.

### **Claim Objections**

Claims 20, 25, 35, 44, 45, 47-49, 51 and 52 remain objected to because they depend from a rejected claim. The basis for this rejection is set forth at page 8 of the previous Office Action (31 May 2006).

### **Conclusion**

Claims 1, 2, 5, 23, 26-30, 39-42, 46, 50 and 53 are rejected.

Claims 20, 25, 35, 44, 45, 47-49, 51 and 52 are objected to.

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

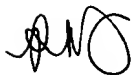
Application/Control Number:  
09/845,717  
Art Unit: 1647


Page 6

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
RMD  
1/25/07

  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
AU1647  
1/30/07